

FEB 13 2007 Bard Balloon Dilation Kit with Tri-Funnel Gastrostomy Tube
Traditional 510(k)

Section 5

510(k) Summary

5.1 General Information

Submitter Name: Bard Access Systems, Inc. (BAS)
[wholly owned subsidiary of C.R. Bard, Inc.]
Address: 5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Telephone Number: (801) 595-0700 ext. 5484
Fax Number: (801) 595-5425
Contact Person: Susan Scott
Date of Preparation: September 15, 2006
Registration Number: 1720496 BAS
2212754 C. R. Bard

5.2 Subject Device Information

Trade Name: Bard® Balloon Dilation Kit with Tri-Funnel Gastrostomy Tube
Common/Usual Name: Percutaneous Gastrostomy Kit with Balloon Dilation Catheter
Classification Name: 78 KNT – Gastrointestinal Tube & Accessories
CFR Reference: 21 CFR §876.5980, Class II
Classification Panel: Gastroenterology/Urology

5.3 Predicate Device Information

Trade Name: Bard® Gauderer™ Universal Percutaneous Endoscopic Gastrostomy
Common/Usual Name: Percutaneous Endoscopic Gastrostomy Kit (PEG Kit)
Classification Name: 78 KNT – Gastrointestinal Tube & Accessories
CFR Reference: 21 CFR §876.5980, Class II
Classification Panel: Gastroenterology/Urology
Premarket Notification: K915841, clearance date 06/25/1993

5.4 Intended Use

The "intended use" is the same for the subject and predicate kit. The kit is intended to be used for non-surgical placement of a feeding device to instill nutritional fluids and/or medication directly into the stomach and/or to decompress the stomach.

5.5 Indications for Use

For initial percutaneous placement of a gastrostomy feeding and/or decompression device into a stoma created by tissue dilation.
Also for percutaneous replacement of a gastrostomy feeding and/or decompression device into an established stoma site.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 1 8 2007

Ms. Susan Scott
Regulatory Affairs Specialist
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K063118
Trade/Device Name: Bard® Balloon Dilation Kit with Tri-Funnel Gastrostomy Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 22, 2007
Received: January 29, 2007

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

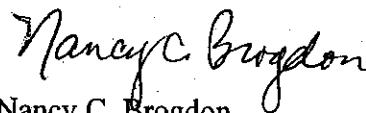
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K063118

Device Name:

Bard® Balloon Dilation Kit with Tri-Funnel Gastrostomy Tube

Indications for Use:

For initial percutaneous placement of a gastrostomy feeding and/or decompression device into a stoma created by tissue dilation.

Also for percutaneous replacement of a gastrostomy feeding and/or decompression device into an established stoma site.

Prescription Use ✓
(Part 21 CFR §801 Subpart D)

~~AND/OR~~

Over-The-Counter Use _____
(21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Spence
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K063118